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August 16, 2007
VIA HAND DELIVERY

DLF 8/20/07

The Honorable Denise Cote
United States District Judge
Southern District New York
500 Pearl Street, Room 1040
New York, NY 10007

Re: *Takeda v. Sandoz*, Civil Action No. 07-3844-DLC (S.D.N.Y.)

Dear Judge Cote:

We represent Defendants Ranbaxy Laboratories Limited and Ranbaxy Pharmaceuticals Inc. ("Ranbaxy") in the consolidated pioglitazone actions pending before Your Honor.[1] We write on behalf of Ranbaxy to request that the Court stay the case entitled, *Takeda v. Sandoz*, Civil Action No. 07-3844-DLC (S.D.N.Y.) ("*Sandoz*"), in order to avoid unjustly depriving Ranbaxy of its exclusivity rights with respect to Takeda's combination use patents, which are at issue in Ranbaxy's case and in the *Sandoz* case.

A. The Hatch-Waxman Act

The Hatch-Waxman Act governs patent challenges by generic drug companies. The Act is a comprehensive statutory framework enacted by Congress to incentivize and reward generic drug companies for expending the considerable resources necessary to challenge weak or invalid drug patents. Under the Act, Ranbaxy is entitled to 180 days of exclusive generic marketing of pioglitazone upon the launch of the product, which will occur upon expiration of the pioglitazone compound patent, because Ranbaxy was one of the first generic companies to challenge Takeda's combination use patents.

If the Court grants Sandoz's motion for judgment on the pleadings with respect to Takeda's combination use patents, Ranbaxy's exclusivity rights for generic pioglitazone would be triggered prematurely, causing Ranbaxy's exclusivity to run prior to its product launch upon expiration of Takeda's patent on the pioglitazone compound. This result would unfairly allow Sandoz to extinguish Ranbaxy's exclusivity rights without compensation. Further, this result

[1] Civil Action Nos. 03-CV-8250, 03-CV-8253, 03-CV-8254, 04-CV-1966.

would undermine a fundamental purpose of the Hatch-Waxman, and unfairly penalize those companies, like Ranbaxy, that properly followed the statutory scheme applicable to such patent challenges.

B. The *Sandoz* Case Should Be Placed on the Same Schedule as Takeda's Case Against Ranbaxy

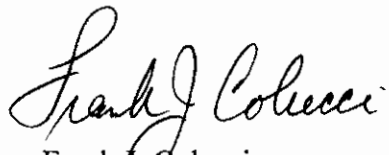
The *Sandoz* case raises the same issues with respect to Takeda's combination use patents as those presented in Takeda's case against Ranbaxy. As such, for reasons of fairness and judicial economy, the *Sandoz* case should be placed on the same schedule as Takeda's case against Ranbaxy.

Takeda's case against Ranbaxy is stayed indefinitely, in view of the Court's earlier decision finding the pioglitazone compound patent valid and infringed by Mylan and Alphapharm. The Federal Circuit affirmed this Court's decision on June 28, 2007. Thus, there can be no generic competition to Takeda's pioglitazone product until 2011, when the compound patent expires. Because sales of generic pioglitazone are not imminent, the Takeda cases against the various generic defendants, including Sandoz, are not ripe for adjudication.

C. Sandoz Has Failed to Offer Any Compelling Reasons for Upending the Hatch-Waxman Act

Sandoz has not presented any compelling reasons for extinguishing Ranbaxy's statutorily-authorized exclusivity rights. Sandoz acknowledges, in fact, that it does not seek to move its case ahead of the Ranbaxy case, and thereby eliminate Ranbaxy's 180-day exclusive marketing period, in order to bring generic competition to the market at an earlier date. Sandoz rather seeks an advantage in scheduling its litigation solely to gain an underserved economic benefit by sharing in the generic drug market during the statutory 180-day exclusivity period that is intended to benefit Ranbaxy and other defendants in the lawsuit. Sandoz has provided no credible argument for usurping this statutory benefit and undermining Congress' intent to reward generic companies that are the first to challenge name brand drug patents. Accordingly, Ranbaxy respectfully requests that the Court refuse to hear Sandoz's motion, pending expiration of the pioglitazone compound patent.

Respectfully Yours,



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